

## PATENT COOPERATION TREATY 10/52375

From the

"ONAL PRELIMINARY EXAMINING AUTHORITY INTERN'

FRIDAY 28 HOV 2004

Davies Collison Cave Level 15 1 Nicholson Street **MELBOURNE VIC 3000** 

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing day/month/year

25 NOV 2004

Applicant's or agent's file reference

12301210/EJH/MLO

IMPORTANT NOTIFICATION

International Application No. PCT/AU2003/001011

International Filing Date 8 August 2003

Priority Date 8 August 2002

Applicant

THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OF MERCY IN QUEENSLAND et al

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the 1. international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all 2. the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report 3. (but not of any annexes) and will transmit such translations to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

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# **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12301210/EJH/MLO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).			
International Application No.	International Filing Date (day/month/year)	le	Priority Date (day/month/year)		
PCT/AU2003/001011	8 August 2003	·	8 August 2002		
International Patent Classification (IPC) or	national classification an	d IPC			
Int. CI. A61K 39/395, A61P 37/06					
Applicant					
THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OF MERCY IN QUEENSLAND et al					
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		44 47 7 -			
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.					
2. This REPORT consists of a total of 3	sheets, including this o	over sheet.			
This report is also accompanied	by ANNEXES, i.e., shee	ts of the description	, claims and/or drawings which have been		
amended and are the basis for th 70.16 and Section 607 of the Ad	is report and/or sheets co ministrative Instructions	intaining rectification under the PCT).	ns made before this Authority (see Rule		
·		٠.	• 1		
These annexes consist of a total	of sheet(s).				
3. This report contains indications relating	g to the following items:				
I X Basis of the report	I X Basis of the report				
II Priority	II Priority				
III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability					
IV Lack of unity of inventi	IV Lack of unity of invention				
V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
VI Certain documents cited	- · · · · · · · · · · · · · · · · · · ·				
VII Certain defects in the ir					
VIII Certain observations on the international application					
Date of submission of the demand		Date of completion	•		
27 February 2004		23 November 200	)4		
Name and mailing address of the IPEA/AU		Authorized Officer			
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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/AU2003/001011

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement			_
Novelty (N)	Claims 5, 9, 10, 14 to 19, 22 and 24 to 32	YES	
	Claims 1 to 4, 6 to 8, 11 to 13, 20, 21 and 23	NO	
Inventive step (IS)	Claims 5, 9, 10, 14 to 19, 22 and 24 to 32	YES	
-	Claims 1 to 4, 6 to 8, 11 to 13, 20, 21 and 23	NO	
Industrial applicability (IA)	Claims 1 to 32	YES	
	Claims nil	МО	

- 2. Citations and explanations (Rule 70.7)
- D1 Prickett, TCR et al, Immunology 1990 (69) pp250 256.
- D2 Hauss, P et al, European Journal of Immunology, 1995 (25) pp2285-2294.
- D3 WO 93/05814 A1 (The General Hospital Corporation) 1 April 1993.
- D4 WO 01/40308 A1 (The Corporation of the Trustees of the Order of the Sisters of Mercy in Queensland) 7 June 2001.
- D5 WO 01/87337 A1 (GPC Biotech AG, Morphosys AG) 22 November 2001
- D6 WO 02/051430 A2 (Synovis Limited) 4 July 2002.
- D7 WO 02/058721 A1 (Baylor College of Medicine) I August 2002.

The invention seems to lie in the specific use of a monoclonal antibody against antigen presenting cells, (APCs) particularly dendritic cells, carrying a CMRF antigen. This feature does not appear in the definitions of claims 1 to 3, 6 to 8 and 11 to 13. Consequently they are not novel and have no inventive step in comparison to D1 and D2 which disclose modulation of the immune activities of dendritic cells.

D3 discloses modulation of antigen presenting cell activity by a protein acting through the interaction of APCs with other cells. The soluble protein may be a monoclonal antibody. Claims 1, 2, 6 to 8, 11, 13, 20, 21 and 23 are not novel and have no inventive step in comparison.

D4 discloses modulation of stimulated dendritic cell activity. The agent may be a monoclonal antibody to CMRF-58. Claims 1, 2, 6 to 8, 11, 13, 20, 21 and 23 are not novel and have no inventive step in comparison.

D5 discloses killing cells which express HLA-DR, an immuno-active substance with an antibody based peptide. Claims 1, 2, 6 to 8, 11 to 14, 20 and 23 are not novel and have no inventive step in comparison. I

D6 discloses stimulation of APCs including dendritic cells by blocking Toll-related receptor signalling and inhibition by enhancement of the same signalling. Claims 1 to 3, 6 to 8, 11 to 13 and 20 are not novel and have no inventive step in comparison.

D7 discloses modulation of myeloid cell activation and immune response by changing DAP12/TREM-1 activity. Claims 1 to 4, 6 to 8, 11 to 13 and 20 are not novel and have no inventive step in comparison.



Creation date: 06-21-2006

Indexing Officer: FPLUMMER1 - FRANK PLUMMER

Team: PUBSImageAssistanceCtr

Dossier: 10525331

Legal Date: 02-22-2005

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